§5.95 Submission of and effective approval dates for abbreviated new animal drug applications and certain new animal drug applications.

The following officials are authorized to perform all the functions of the Commissioner of Food and Drugs with regard to decisions made under section 512(c)(2)(D)(iv) and (c)(2)(F) of the Federal, Food, Drug, and Cosmetic Act (the act) concerning the date of submission and the date of effective approval of abbreviated new animal drug applications including supplements thereto, submitted under section 512(b)(2) of the act, and of new animal drug applications including supplements thereto, submitted under section 512(b)(1) of the act:

(a) The Director and Deputy Director, Center for Veterinary Medicine (CVM).

(b) The Director and Deputy Director, Office of New Animal Drug Evaluation, CVM.

[56 FR 6263, Feb. 15, 1991]

§5.98 Authority relating to medical device reporting procedures.

(a) The Director and Deputy Directors, Center for Devices and Radiological Health (CDRH), and the Director and Deputy Director, Office of Surveillance and Biometrics, CDRH, are authorized to approve electronic reporting under §803.14 of this chapter.

(b) The Director and Deputy Directors, Center for Devices and Radiological Health (CDRH), and the Director and Deputy Director, Office of Surveillance and Biometrics, CDRH, are authorized to request the submission of additional information under §803.15 of this chapter.

(c) The Director and Deputy Directors, Center for Devices and Radiological Health (CDRH), and the Director and Deputy Director, Office of Surveillance and Biometrics, CDRH, are authorized to grant or revoke exemptions and variances from reporting requirements under §803.19 of this chapter.

[60 FR 63607, Dec. 11, 1995]

§5.99 Issuance of notices relating to proposals and orders for debarment and denial of an application to terminate debarment.

The Director and Deputy Director, Center for Drug Evaluation and Research (CDER), the Director and Deputy Director, Center for Veterinary Medicine (CVM), and the Director and Associate Director for Policy Coordination and Public Relations, Center for Biologics Evaluation and Research (CBER) are authorized to issue the following notices under section 306 of the Federal Food, Drug, and Cosmetic Act (the act) which relate to the assigned functions of their organizations:

(a) Notices of opportunity for hearing on proposals for mandatory or permissive debarment.

(b) Notices ordering debarment when opportunity for a hearing has been waived.

(c) Notices ordering debarment where the person notifies the agency that the person acquiesces to debarment under section 306(c)(2)(B) of the act.

(d) Notices of opportunity for hearing on proposals denying an application to terminate debarment under section 306(d)(3) of the act.

(e) Orders denying an application to terminate debarment under section 306(d)(3) of the act when opportunity for a hearing has been waived.

[61 FR 8215, Mar. 4, 1996; 61 FR 11545, Mar. 21, 1996; 61 FR 14375, Apr. 1, 1996]

Subpart C—Organization

§5.100 Headquarters.

The central organization of the Food and Drug Administration consists of the following:

OFFICE OF THE COMMISSIONER[1]

IMMEDIATE OFFICE

Office of the Administrative Law Judge.
Office of Executive Operations.
Office of Equal Employment Opportunity and Civil Rights.
Office of Chief Counsel.
Office of Internal Affairs.

[1] Mailing address: 5600 Fishers Lane, Rockville, MD 20857.

OFFICE OF EXTERNAL AFFAIRS

Office of AIDS and Special Health Issues.
Office of Consumer Affairs.
Office of Health Affairs.
Office of Legislative Affairs.
Office of Public Affairs.
Office of Women's Health.

OFFICE OF MANAGEMENT AND SYSTEMS

Office of Planning and Evaluation.
Office of Management.
Office of Information Resources Management.

OFFICE OF POLICY

Regulations Policy and Management Staff.
Policy Development and Coordination Staff.
Policy Research Staff.
International Policy Staff.

OFFICE OF OPERATIONS

OFFICE OF BIOTECHNOLOGY

OFFICE OF ORPHAN PRODUCTS DEVELOPMENT

NATIONAL CENTER FOR TOXICOLOGICAL RESEARCH[2]

Office of the Center Director

Environmental Health and Program Assurance Staff.
Scientific Coordination Staff.
Equal Employment Opportunity Staff.
Technology Advancement Staff.

Office of Planning and Resource Management

Planning Staff.
Financial Management Staff.
Evaluation Staff.

Office of Research

Division of Reproductive and Developmental Toxicology.
Division of Genetic Toxicology.
Division of Biochemical Toxicology.
Division of Nutritional Toxicology.
Division of Biometry and Risk Assessment.
Division of Chemistry.
Division of Microbiology.
Division of Neurotoxicology.

Office of Research Support

Veterinary Services Staff.
Information Technology Staff.
Division of Administrative Services.
Division of Facilities Engineering and Maintenance.

[2] Mailing address: Jefferson, AR 72079–9502.

OFFICE OF REGULATORY AFFAIRS

Office of the Associate Commissioner

Contaminants Policy Coordination Staff.
Equal Employment Opportunity Staff.
Strategic Initiatives Staff.

Office of Resource Management

Division of Planning, Evaluation, and Management.
Division of Information Systems.
Division of Human Resource Development.
Division of Management Operations.

Office of Enforcement

Division of Compliance Management and Operations.
Division of Compliance Policy.
Division of Medical Products Quality Assurance.

Office of Regional Operations

Division of Federal-State Relations.
Division of Field Science.
Division of Field Investigations.
Division of Emergency and Epidemiological Operations.
Division of Import Operations and Policy.

Office of Criminal Investigations[3]

Northeast Area Office.[4]
Mid-Atlantic Area Office.[3]
Southeast Area Office.[5]
Midwest Area Office.[6]
Southwest Area Office.[7]
Pacific Area Office.[8]

CENTER FOR BIOLOGICS EVALUATION AND RESEARCH[9]

Office of the Center Director

Equal Employment and Minority Recruitment Staff.
Congressional and Public Affairs Staff.
Scientific Advisors and Consultants Staff.

[3] Mailing address: 7500 Standish Pl., rm. 250N, Rockville, MD 20855.

[4] Mailing address: 10 Exchange Pl., 18th floor, Jersey City, NJ 07302.

[5] Mailing address: 8525 NW 53d Terrace, suite 204, Miami, FL 33166.

[6] Mailing address: 3 Arboretum 801 Warrenville Rd., suite 550, Lisle, IL 60532.

[7] Mailing address: 10901 West 84th Terrace, suite 201, Lenexa, KS 66214–3338.

[8] Mailing address: 4365 Executive Dr., suite 230, San Diego, CA 92122.

[9] Mailing address: 1401 Rockville Pike, suite 200N, Rockville, MD 20852–1448.

Office of Management

Division of Management and Budget.
Division of Scientific and Management Information Systems.
Division of Administrative Management.

Office of Compliance

Division of Case Management.
Division of Bioresearch Monitoring and Regulations.
Division of Inspection and Surveillance.

Office of Therapeutics Research and Review

Division of Cytokine Biology.
Division of Cellular and Gene Therapies.
Division of Hematologic Products.
Division of Monoclonal Antibodies.
Division of Clinical Trial Design and Analysis.
Division of Application Review and Policy.

Office of Vaccines Research and Review

Division of Allergenic Products and Parasitology.
Division of Bacterial Products.
Division of Viral Products.
Division of Vaccines and Related Products Applications.

Office of Establishment Licensing and Product Surveillance

Division of Product Quality Control.
Division of Veterinary Services.
Division of Biostatistics and Epidemiology.
Division of Establishment Licensing.

Office of Blood Research and Review

Division of Blood Applications.
Division of Transfusion Transmitted Diseases.
Division of Hematology.

CENTER FOR DRUG EVALUATION AND RESEARCH[1]

Office of the Center Director

Pilot Drug Evaluation Staff.
Advisors and Consultants Staff.
Professional Development Staff.
CDER Executive Secretariat Staff.
Equal Employment Opportunity Staff.

Office of Management

Division of Drug Information Resources.
Division of Information Systems Design.
Medical Library.
Division of Management and Budget.

Office of Compliance

Division of Drug Quality Evaluation.
Division of Drug Labeling Compliance.
Division of Manufacturing and Product Quality.
Division of Scientific Investigations.
Division of Regulatory Affairs.

Office of Drug Evaluation I

Division of Cardio-Renal Drug Products.
Division of Oncology and Pulmonary Drug Products.
Division of Neuropharmacological Drug Products.
Division of Medical Imaging, Surgical, and Dental Drug Products.
Division of Gastrointestinal and Coagulation Drug Products.

Office of Drug Evaluation II

Division of Anti-Infective Drug Products.
Division of Metabolism and Endocrine Drug Products.
Division of Anti-Viral Drug Products.
Division of Topical Drug Products.

Office of Drug Standards

Division of Drug Marketing, Advertising, and Communications.

Office of Epidemiology and Biostatistics

Division of Epidemiology and Surveillance.
Division of Biometrics.

Office of Generic Drugs[10]

Division of Chemistry I.
Division of Chemistry II.
Division of Bioequivalence.
Division of Labeling and Program Support.

Office of Over-the-Counter Drug Evaluation

Monograph Review Staff.
OTC Drug Policy Staff.
Medical Review Staff.

Office of Research Resources

Division of Research and Testing.
Division of Biopharmaceutics.
Division of Drug Analysis.
Division of Clinical Pharmacology.

CENTER FOR DEVICES AND RADIOLOGICAL HEALTH[11]

Office of the Center Director

Office of Management Services

Division of Planning, Evaluation, and Information Services.
Division of Resource Management.

[10] Mailing address: 7500 Standish Pl., rm. 150, Rockville, MD 20855.

[11] Mailing address: 2094 Gaither Rd., Rockville, MD 20850.

Office of Health Physics[11]

Office of Health and Industry Programs[12]

Office of Standards and Regulations[11]

Office of Information Systems[13]

Division of Computer Services.
Division of Information Resources.

Office of Compliance[11]

Division of Program Operations.
Division of Bioresearch Monitoring.
Division of Enforcement 1.
Division of Enforcement 2.
Division of Enforcement 3.

Office of Device Evaluation[12]

Division of Cardiovascular, Respiratory and Neurological Devices.
Division of Reproductive, Abdominal, Ear, Nose, and Throat, and Radiological Devices.
Division of General and Restorative Devices.
Division of Clinical Laboratory Devices.[17]
Division of Ophthalmic Devices.

Office of Science and Technology[1]

Division of Mechanics and Materials Science.
Division of Life Sciences.
Division of Physical Sciences.
Division of Electronics and Computer Science.
Division of Management, Information, and Support Services.

Office of Health and Industry Programs

Division of Device User Programs and Systems Analysis.
Division of Small Manufacturers Assistance.
Division of Mammography Quality and Radiation Programs.
Division of Communication Media.

Office of Surveillance and Biometrics[12]

Division of Biostatistics.[14]
Division of Postmarket Surveillance.
Division of Surveillance Systems.

CENTER FOR FOOD SAFETY AND APPLIED NUTRITION[15]

Office of the Center Director

Office of Policy, Planning, and Strategic Initiatives.

OFFICE OF PROGRAMS

Office of Cosmetics and Colors

Division of Programs and Enforcement Policy.
Division of Science and Applied Technology.

Office of Food Labeling

Division of Programs and Enforcement Policy.
Division of Technical Evaluation.
Division of Science and Applied Technology.

Office of Pre-Market Approval

Division of Product Policy.
Division of Petition Control.
Division of Health Effects Evaluation.
Division of Molecular Biological Research and Evaluation.
Division of Product Manufacture and Use.

Office of Plant and Dairy Foods and Beverages

Division of Programs and Enforcement Policy.
Division of Microanalytical Evaluations.
Division of Virulence Assessment.
Division of Pesticides and Industrial Chemicals.
Division of Natural Products.
Division of Food Processing and Packaging.

Office of Seafood

Division of Special Programs.
Division of Programs and Enforcement Policy.
Division of Science and Applied Technology.

Office of Special Nutritionals

Division of Programs and Enforcement Policy.
Division of Science and Applied Technology.

Office of Special Research Skills

Division of Toxicological Research.
Division of Microbiological Studies.

OFFICE OF SYSTEMS AND SUPPORT

Quality Assurance Staff.

Office of Constituent Operations

Consumer Education Staff.
Legislative Activities Staff.
Industry Activities Staff.
International Activities Staff.

Office of Field Programs

Division of Enforcement.
Division of HACCP Programs.
Division of Cooperative Programs.
Division of Field Program Planning and Evaluation.

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[12] Mailing address: 9200 Corporate Blvd., Rockville, MD 20850.
[13] Mailing address: 2098 Gaither Rd., Rockville, MD 20850.
[17] See footnote 13.
[14] Mailing address: 9200 Corporate Blvd., Rockville, MD 20850.
[15] Mailing address: 200 C St. SW., Washington, DC 20204.

Office of Management Systems

Division of Management Services and Policy.
Division of Planning and Financial Management.
Division of Information Resources Management.
Division of Administrative Services.

Office of Scientific Analysis and Support

Division of Mathematics.
Division of General Scientific Support.
Division of Market Studies.

CENTER FOR VETERINARY MEDICINE[16]

Office of the Center Director

Office of Management

Division of Program and Information Systems.
Division of Program Communications and Administrative Management.

Office of Surveillance and Compliance

Division of Compliance.
Division of Animal Feeds.
Division of Surveillance.
Division of Voluntary Compliance and Hearings Development.

Office of New Animal Drug Evaluation

Division of Biometrics and Production Drugs.
Division of Chemistry.
Division of Therapeutic Drugs for Food Animals.
Division of Therapeutic Drugs for Non-Food Animals.
Division of Toxicology and Environmental Sciences.

Office of Science

Division of Residue Chemistry.
Division of Animal Research.

[60 FR 16568, Mar. 31, 1995, as amended at 61 FR 8472, Mar. 5, 1996]

§5.105 Chief Counsel, Food and Drug Administration.

The Chief Counsel to the Commissioner of Food and Drugs is the Associate General Counsel, Food and Drug Division, Office of the General Counsel, Department of Health and Human Services, Room 6–57, 5600 Fishers Lane, Rockville, MD 20857.

[46 FR 8455, Jan. 27, 1981, as amended at 56 FR 8709, Mar. 1, 1991]

§5.110 FDA Public Information Offices.

(a) *Dockets Management Branch (HFA–09305).* The Dockets Management Branch Public Room is located in rm. 1–23, 12420 Parklawn Dr., Rockville, MD 20857. Telephone: 301–443–1753.

(b) *Freedom of Information Staff (HFI–0935).* The Freedom of Information Public Room is located in Room 12A–30, Parklawn Building, 5600 Fishers Lane, Rockville, MD 20857. Telephone: 301–443–6310.

(c) *Press Relations Staff (HFI–0940).* Press Offices are located in Room 15–05, Parklawn Building, 5600 Fishers Lane, Rockville, MD 20857. Telephone: 301–443–3285; and in Room 3807, FB–8, 200 C Street SW., Washington, DC 20204. Telephone: 202–245–1144.

[46 FR 8455, Jan. 27, 1981, as amended at 54 FR 9034, Mar. 3, 1989; 59 FR 14363, Mar. 28, 1994]

§5.115 Field structure.

NORTHEAST REGION

Regional Field Office: 830 Third Ave., Brooklyn, NY 11232.
Northeast Regional Laboratory: 850 Third Ave., Brooklyn , NY 11232.
New York District Office: 850 Third Ave., Brooklyn, NY 11232.
Boston District Office: One Montvale Ave., Stoneham, MA 02180.
Buffalo District Office: 599 Delaware Ave., Buffalo, NY 14202.

MID-ATLANTIC REGION

Regional Field Office: 900 U.S. Customhouse, Second and Chestnut Sts., Philadelphia, PA 19106.
Philadelphia District Office: 900 U.S. Customhouse, Second and Chestnut Sts., Philadelphia, PA 19106.
Baltimore District Office: 900 Madison Ave., Baltimore, MD 21201.
Cincinnati District Office: 1141 Central Pkwy., Cincinnati, OH 45202–1097.
Newark District Office: Waterview Corporate Center, 10 Waterview Blvd., 3d floor, Parsippany, NJ 07054.

[16] Mailing address: 7500 Standish Pl., Rockville, MD 20855.